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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,370	03/15/2001	Yukino Owaki	204395US0XPC	7568

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,370

Applicant(s)

OWAKI ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, and 10-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Rule 1.132 Declaration, Extension of Time, Foreign Priority Papers, and Amendments received on January 29, 2004 is acknowledged. Receipt of additional Foreign Priority Papers received on February 11, 2004 is acknowledged. Claims 1-5, 7, and 10-19 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-5, 7, and 10-19 under 35 U.S.C. 103(a) as being unpatentable over Yuutoku Yakuhin Kogyo KK (JP 10-147521) in view of Kubo et al (5,827,528) is maintained.

JP discloses a cataplasm for reducing pain containing 1-30% lidocaine, 5-50% SIS, 5-60% liquid paraffin, and 1-60% alicyclic saturated hydrocarbon resin on a flexible base material. See page 1. The formulation may contain softeners such as polybutene

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and polyisobutylene. The inclusion of antioxidants and bulking agents such as titanium dioxide is also taught. See page 3. The base material has a thickness of 50-500 microns. See page 3.

JP does not specify the weight percent of butyl rubber in the formulation.

Kubo et al teaches a medical adhesive composition. The composition contains a thermoplastic elastomer such as SIS, a low compatibility thermoplastic elastomer such as butyl rubber/polyisobutene, a softener, and tackifier. Kubo teaches the tackifier may be a hydrocarbon resin, petroleum resin, or a terpene-phenol resin (col. 5, lines 15-28). Further, Kubo teaches the manipulation of the elastomers and softeners in the composition wherein the softener lowers the hardness of the elastomer. If the hardness is too high then the adhesive composition will not fit well on the skin (col. 6, lines 17-37). Note also embodiment 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yuutoku Yakuhin Kogyo KK and Kubo et al and utilize butyl rubber in instant amount. One would be motivated to do so since Kubo teaches instant amount of polyisobutylene (butyl rubber) as thermoplastic elastomers for utilization with SIS in a pressure sensitive adhesive. Additionally, Kubo teaches the motivation of manipulating the amounts of the elastomers, softener, and tackifiers in the adhesive composition. Furthermore since Kubo teaches a similar pressure sensitive adhesive patch with similar components as JP and JP teaches the inclusion of a butylene rubber, a skilled artisan would expect similar results and success by combining the teachings of the two references.

*Note claims 2-5 and 10 have functional limitations on the product claims; therefore they do not hold patentable weight since the functional limitation does not recite a structural limitation on the product itself.

Response to Amendment

The Declaration under 37 CFR 1.132 filed January 29, 2004 is insufficient to overcome the rejection of claims 1-5, 7, and 10-19 based upon Yuutoku Yakuhin Kogyo KK (JP 10-147521) in view of Kubo et al (5,827,528) as set forth in the last Office action because: Firstly, the applicant has not compared the closest prior art. For instance, applicant has taken the teachings of the secondary reference, Kubo et al, and made a comparison when the rejection is based on JP in view of Kubo et al. JP teaches the broad aspect of the invention and thus applicant needs to submit data comparing JP and instant invention. The examiner points out that JP teaches all the critical elements and percentages except for the butyl rubber. Thus, Kubo et al is relied upon to cure this deficiency by teachings the manipulation of the concentration of the rubber. In order to overcome the instant rejection, the applicant must submit evidence showing the criticality of the concentration of the butyl rubber and the lack of obviousness in manipulating it.

However, for the record the examiner will note the following: it is pointed out that the comparative test preparations and the inventive preparations have different concentrations of the additives (SIS, butyl rubber, the alicyclic saturated hydrocarbon rubber, liquid paraffin, and lidocaine). For instance, applicant utilizes 22% SIS in the inventive composition and 15.4% in the comparative. Thus, a proper comparison cannot

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be made since the results may be due to the concentration of the other components in the composition and not the water-absorbing additive. Secondly, applicant is demonstrating the degree of the adhesiveness (which is not claimed) and not the adverse affect the component has on the composition. The declaration in fact does not demonstrate the adverse affect of the water-absorbing component since the test demonstrated that the preparation had the ability to not adhere to the skin. Furthermore, the results demonstrate adhesiveness when the tape is immersed in water and not adhesiveness during typical wear.

Response to Arguments

Applicant argues that the claim language has been amended to recite a non-aqueous tape and to "consisting essentially of" claims language to exclude any components that materially affect the composition. Applicant argues that Kubo et al teach a water-absorbing component that may materially affect the composition.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it is noted that applicant does not argue the merits of the primary reference, JP 10-147521. The instant amendments to the claims language does not overcome the rejection since the examiner points outs that JP teaches a non-aqueous tape preparation with all elements and does not teach any element that would materially affect the composition. Further, JP provides comparison compositions that do have aqueous material and states that these compositions are inferior and do not adhere well to the skin. Therefore, JP teaches applicant's inventive concept.

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The only deficiency in JP is the concentration of the butyl rubber. Kubo et al is relied upon for its *specific* teaching of manipulating softeners such as liquid rubber and not the teaching of water-absorbing components since clearly JP teaches all the required components. Kubo teaches that the concentration of the liquid rubber is based on the thermoplastic elastomer (SIS) whereby the hardness of the elastomer can be lowered to the desired softness with the use of a softener such as liquid rubber. Furthermore, Kubo teaches that if the rubber is not in a proper ratio then the hardness of the elastomer is too high and will not fit well on the patient's skin. Kubo teaches if the softener is in an excessive amount, then the softener and the elastomer do not dissolve into each other and separate out. Therefore, clearly Kubo teaches the guidelines for manipulating the amount of softener in the composition. It is the examiner's position that it is known in the art to manipulate the amount of softener depending on the desired effect and softness. Further, applicant has not submitted any evidence demonstrating the criticality of the concentration of the butyl rubber.

It should be noted that applicant's assertion that the instant claim language excludes water-absorbing components is incorrect. The claims exclude water or any component that would affect the basic composition. However, applicant has not shown that all water-absorbing components materially affect the composition since clearly the comparative preparation had the ability to adhere to skin and stay on the skin for a time period. Therefore, they do not affect the composition. Applicant is demonstrating the degree of adhesiveness in water and not its adverse effect in the composition.

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Lastly in regards to the molecular weight of the butyl rubber, the examiner points out that column 4, lines 39-45 wherein high molecular weight butyl rubbers such as Kuraprene IR-10 (a MW of 850,000) are taught. The examiner cites US patent 4,532,298, column 61, as art of interest, wherein the MW of Kuraprene IR-10 is disclosed.

Therefore, the rejections are maintained.

Rejection of claims 1-5, 7, and 10-19 under 35 U.S.C. 103(a) as being unpatentable over Sekisui Chem Co (JP 07-126157) in view of Kubo et al (5,827,528) is maintained.

JP teaches a percutaneous absorption tape for lidocaine. The formulation contains 40 weight section SIS, 20 weight section an alicyclic hydrocarbon resin, 40 weight percent liquid paraffin, and lidocaine. The formulation is placed on a film of 40 microns. See table 1. JP teaches an antioxidant in the formulation. The rubber system taught contains SIS and other rubbers such as polybutene, polyisoprene, isobutylene isoprene rubber, and natural rubber. See page 2.

JP does not specify the weight percent of butyl rubber in the formulation.

Kubo et al teaches a medical adhesive composition. The composition contains a thermoplastic elastomer such as SIS, a low compatibility thermoplastic elastomer such as butyl rubber/polyisobutene, a softener, and tackifier. Kubo teaches the tackifier may be a hydrocarbon resin, petroleum resin, or a terpene-phenol resin (col. 5, lines 15-28). Further, Kubo teaches the manipulation of the elastomers and softeners in the composition wherein the softener lowers the hardness of the elastomer. If the hardness

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is too high then the adhesive composition will not fit well on the skin (col. 6, lines 17-37).

Note also embodiment 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of JP and Kubo et al and utilize butyl rubber in instant amount. One would be motivated to do so since Kubo teaches instant amount of polyisobutylene (butyl rubber) as thermoplastic elastomers for utilization with SIS in a pressure sensitive adhesive. Additionally, Kubo teaches the motivation of manipulating the amounts of the elastomers, softener, and tackifiers in the adhesive composition. Furthermore since Kubo teaches a similar pressure sensitive adhesive patch with similar components as JP and JP teaches the inclusion of a butylene rubber, a skilled artisan would expect similar results and success by combining the teachings of the two references.

*Note claims 2-5 and 10 have functional limitations on the product claims; therefore they do not hold patentable weight since the functional limitation does not recite a structural limitation on the product itself.

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The Declaration under 37 CFR 1.132 filed January 29, 2004 is insufficient to overcome the rejection of claims 1-5, 7, and 10-19 based upon Yuutoku Yakuhin Kogyo KK (JP 10-147521) in view of Kubo et al (5,827,528) as set forth in the last Office action because: Firstly, the applicant has not compared the closest prior art. For instance, applicant has taken the teachings of the secondary reference, Kubo et al, and made a comparison when the rejection is based on JP in view of Kubo et al. JP teaches the

broad aspect of the invention and thus applicant needs to submit data comparing JP and instant invention. The examiner points out that JP teaches all the critical elements and percentages except for the butyl rubber. Thus, Kubo et al is relied upon to cure this deficiency by teachings the manipulation of the concentration of the rubber. In order to overcome the instant rejection, the applicant must submit evidence showing the criticality of the concentration of the butyl rubber and the lack of obviousness in manipulating it.

However, for the record the examiner will note the following: it is pointed out that the comparative test preparations and the inventive preparations have different concentrations of the additives (SIS, butyl rubber, the alicyclic saturated hydrocarbon rubber, liquid paraffin, and lidocaine). For instance, applicant utilizes 22% SIS in the inventive composition and 15.4% in the comparative. Thus, a proper comparison cannot be made since the results may be due to the concentration of the other components in the composition and not the water-absorbing additive. Secondly, applicant is demonstrating the degree of the adhesiveness (which is not claimed) and not the adverse affect the component has on the composition. The declaration in fact does not demonstrate the adverse affect of the water-absorbing component since the test demonstrated that the preparation had the ability to not adhere to the skin. Furthermore, the results demonstrate adhesiveness when the tape is immersed in water and not adhesiveness during typical wear.

Response to Arguments

Applicant argues that the claim language has been amended to recite a non-aqueous tape and to "consisting essentially of" claims language to exclude any components that materially affect the composition. Applicant argues that Kubo et al teach a water absorbing component that may materially affect the composition.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it is noted that applicant does not argue the merits of the primary reference, JP 07-126157. The instant amendments to the claims language does not overcome the rejection since the examiner points out that JP teaches a non-aqueous tape preparation with all elements and does not teach any element that would materially affect the composition.

The only deficiency in JP is the concentration of the butyl rubber. Kubo et al is relied upon for its *specific* teaching of manipulating softeners such as liquid rubber and not the teaching of water-absorbing components since clearly JP teaches all the required components. Kubo teaches that the concentration of the liquid rubber is based on the thermoplastic elastomer (SIS) whereby the hardness of the elastomer can be lowered to the desired softness with the use of a softener such as liquid rubber. Furthermore, Kubo teaches that if the rubber is not in a proper ratio then the hardness of the elastomer is too high and will not fit well on the patient's skin. Kubo teaches if the softener is in an excessive amount, then the softener and the elastomer do not dissolve into each other and separate out. Therefore, clearly Kubo teaches the guidelines for manipulating the amount of softener in the composition. It is the examiner's position that it is known in the art to manipulate the amount of softener depending on the desired

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effect and softness. The applicant has not submitted any evidence demonstrating the criticality of the concentration of the butyl rubber.

It should be noted that applicant's assertion that the instant claim language excludes water-absorbing components is incorrect. The claims exclude water or any component that would affect the basic composition. However, applicant has not shown that all water-absorbing components materially affect the composition since clearly the comparative preparation had the ability to adhere to skin and stay on the skin for a time period. Therefore, they do not affect the composition. Applicant is demonstrating the degree of adhesiveness in water and not its adverse effect in the composition.

Lastly in regards to the molecular weight of the butyl rubber, the examiner points out that column 4, lines 39-45 wherein high molecular weight butyl rubbers such as Kuraprene IR-10 (a MW of 850,000) are taught. The examiner cites US patent 4,523,024, column 61, as art of interest, wherein the MW of Kuraprene IR-10 is disclosed.

Therefore, the rejections are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 8, 2004

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